510(k) Summary of Safety and Effectiveness

OCT 23 2012

Submitter Information:

Name:	Surgical Solutions, a global business unit of Covidien
Address:	60 Middletown Avenue North Haven, CT 06473
Name of contact person:	Renee Borgesano Manager, Regulatory Affairs Covidien Phone: (203) 492-5325 Fax: (203) 492-5029
Establishment Registration:	1219930
Date prepared:	September 27, 2012

Name of device:

Trade or proprietary name:	AbsorbaTack™ Absorbable Fixation Device
Common or usual name:	Absorbable Tack and Applicator
Classification name:	Implantable Staple
Device Classification:	Pursuant to 21 CFR 878.4750, this product is a Class II device.
Classification panel:	General and Plastic Surgery (79)
Regulation:	21 CFR 878.4750
Product Code:	GDW
Reason for 510(k) submission:	To obtain premarket clearance for the change in the design of the AbsorbaTack™ Absorbable Fixation Device with no changes in the indications or intended use of the device.
Predicate Device(s):	AbsorbaTack™ Absorbable Fixation Device (K090470)
Device description:	AbsorbaTack™ Absorbable Fixation Devices are sterile single use devices for the fixation of prosthetic material such as hernia mesh to soft tissue. The Tack is constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid and is dyed with D&C violet #2. The device is offered with 5, 10, 15, 20, or 30 tacks.
Intended use of the device:	AbsorbaTack™ Absorbable Fixation Devices are intended for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures such as hernia repair.
Technological characteristics:	AbsorbaTack™ Absorbable Fixation device is similar to the predicate device except for the revised shaft design. The design modifications include adding a flex cable in the inner drive tube of the shaft to allow for continuous rotation if the outer tube is bent to ensure tack deployment, shortening an existing stiffener to reinforce the interface between the outer shaft tube and the body

	halves, and extending the spring up the entire length of the outer shaft tube that is outside of the body halves.
Material characteristics:	Devices are comprised of materials which have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices – Part 1, Evaluation and Testing and is identical to the predicate device. No new materials are introduced in the proposed device.
Performance data:	There has been no change to the performance specifications of the AbsorbaTack™ Absorbable Fixation Device. The modified design does not change the performance of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 23 2012

Covidien
% Ms. Renee Borgesano
Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K123109
Trade/Device Name: ABSORBATACK™ Absorbable Fixation Device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 03, 2012
Received: October 04, 2012

Dear Ms. Borgesano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123109

Device Name: ABSORBATACK™ Absorbable Fixation Device

Indications For Use:

The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraus for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K123109